

REMARKS

This Amendment is in response to the outstanding Official Action mailed June 19, 2002, the shortened statutory period for response having expired on September 19, 2002. In this regard, Applicants submit herewith a three-month extension petition resetting the deadline for responding to the Official Action to and including December 19, 2002. In view of the below remarks, reconsideration of the Examiner's rejection is respectfully requested.

The Examiner has objected to the drawings under 37 C.F.R. § 1.83(a) as not disclosing a computer navigation system. Applicants submit herewith proposed drawing corrections depicting a computer navigation system as described in the specification. This, as well as the other proposed revisions to the drawings, as indicated in red, do not introduce new matter. Upon notice of acceptance of the proposed changes, Applicants will submit substitute formal drawings.

Applicants have amended claims 3, 18 and 31 to overcome the issues raised by the Examiner with respect to the term "infinitely variable" and providing antecedent basis for "said tibial anchoring means." Accordingly, the aforementioned issues raised by the Examiner have been overcome, and notice to that effect is respectfully requested.

The application, as filed, included claims 1-42, directed to a system for guiding the resection of a bone during arthroplasty, of which claims 1, 16 and 28 have been represented in independent form. The Examiner has rejected claims 1-4, 8, 9, 11, 12, 16-18, 21, 23, 24, 28, 30, 32, 33 and 36-39 under 35 U.S.C. § 103(a) as being unpatentable over *Morawa et al.*, U.S. Patent No. 5,788,700 in view of *Matsen, III et al.*, U.S. Patent No. 5,690,635. The remaining claims have been designated by the Examiner as allowable if rewritten into independent form.

Morawa et al. discloses an alignment assembly 70 (see Fig. 1) which includes an upper shaft portion 40 telescopically received in a lower tube member 46 which allows for proximal-distal movement of the resection guide 90 with respect to the anchoring clamp 60. A first carriage 72 allows for interior-posterior sliding movement along a first guideway 74 which is carried by second carriage 76 allowing for medial-lateral sliding movement along a second guideway 78. The Examiner recognizes that the alignment assembly of Morawa et al. only provides three translational adjustments. Contrary to the teachings of Morawa et al., Applicants' claimed alignment guide provides three degrees of freedom of motion, i.e., two rotational and one translational. The Examiner recognizes this features as distinguishing Applicants' invention over Morawa et al., hence, the Examiner's designation of dependent claim 4 as being allowable if rewritten in independent form.

Independent claims 1, 16 and 28 present Applicants' alignment guide in "means-plus-function" format. Specifically, the claims recite "alignment means for locating the resection guide relative to the anchoring means." On this issue, the Examiner's attention is directed to the Federal Circuit decision in *In re Donaldson Company, Inc.*, 16 F.3d 1189 (Fed. Cir. 1994) *en banc*. The Federal Circuit held that §112(6) applies not only in infringement determinations, but also in patentability determinations. It is well established that claims are to be given their broadest reasonable interpretation during prosecution. However, the Federal Circuit's decision set a limit on how broadly the United States Patent and Trademark Office can construe means-plus-function language under the rubric of reasonable interpretation. Specifically, the Federal Circuit held that the broadest reasonable interpretation that an Examiner may give means-plus-function language is that statutorily mandated in §112(6). Therefore, one must construe

means-plus-function language in a claim by looking to the specification and interpret that language in light of the corresponding structure, material, or acts described therein, and equivalence thereof. Accordingly, the Examiner may not disregard the structure disclosed in Applicants' specification corresponding to the means-plus-function language when rendering a patentability determination.

Applicants' alignment guide, such as shown in Fig. 5 and as described in Applicants' specification on page 5, lines 1 *et seq.*, is distinguished over the alignment guide in *Morawa et al.* by providing a structure to accommodate two rotational and one translational motions. As *Morawa et al.* discloses the construction of an alignment guide which provides only translational motion, there is no disclosure of an alignment guide which would anticipate Applicants' claimed alignment guide. Accordingly, the Examiner's rejection is considered traversed and should therefore be withdrawn.

Applicants' newly proposed claims 43-73 are also directed to a system for guiding the resection of a patient's bone during arthroplasty, of which claims 43, 50, 57 and 64 have been presented in independent form. These claims are distinguished over *Morawa et al.* by including limitations which the Examiner has acknowledged as being directed to allowable subject matter. Specifically, independent claim 43 includes an alignment guide having a first, second and third assembly for positioning the resection guide along a translational path, a first rotational path and a second rotational path, respectively. Independent claims 30 and 57 include an alignment guide having a first and second assembly, the first assembly positioning the resection guide along a translational path, and the second assembly positioning the resection guide along first and second rotational paths. Finally, claim 64 includes an alignment guide for positioning the resection guide along a

translational path and along a plurality of rotational paths. As these limitations of Applicants' claimed alignment guide are not disclosed in *Morawa et al.*, notice of allowance of claims 43-73 are respectively requested.

In considering Applicants' within response, Applicants designate the rejected dependent claims as being allowable by virtue of their ultimate dependency upon submittedly allowable independent claims. Although Applicants have not separately argued the patentability of each of the dependent claims, Applicants' failure to do so is not to be taken as an admission that the features of the dependent claims are not themselves separably patentable over the prior art cited by the Examiner.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "Version with markings to show changes made".

The Examiner's attention is directed to Applicants' co-pending United States Patent Application Nos. 09/811,318; 09/811,043; and 09/811,211; all filed March 17, 2001.

As it is believed that all of the rejections set forth in the Official Action have been fully met, favorable reconsideration and allowance are earnestly solicited.

If, however, for any reason the Examiner does not believe that such action can be taken at this time, it is respectfully requested that he telephone Applicants' attorney at (908) 654-5000 in order to overcome any additional objections which he might have.

Application No.: 09/811,042

Docket No.: OSTEONICS 3.0-414 III

If there are any additional charges in connection with this requested amendment, the Examiner is authorized to charge Deposit Account No. 12-1095 therefor.

Dated: December 17, 2002

Respectfully submitted,

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VERSION SHOWING MARKED UP CHANGES

IN THE SPECIFICATION

At page 12, lines 12-26:

Referring now to Figures 5-7, the exemplary depicted resection guide 14 has a cutting guide surface 14a, an attachment rod 14b, a pair of connectors 14c, 14d for connecting trackers 100 ~~(not shown)~~, a pair of rotatable pin guides 14e, 14f, and a pair of fail safe mounting bores 14g, 14h.

The resection guide 14 is attached to the alignment guide 12 by opening cam lock 12c and inserting the attachment rod 14b into the alignment guide. It will be appreciated by those skilled in the art that the cam lock 12c allows proximal-distal positioning of the resection guide 14. After the resection guide 14 is attached to the alignment device 12, a tracker 100 is attached to the guide 14.

IN THE CLAIMS

3. (AMENDED) A system according to claim 1 wherein said three degrees of freedom are infinitely adjustable ~~variable~~.

4. (AMENDED) A system according to claim 1 wherein said anchoring means comprises ~~is~~ a pin.

8. (AMENDED) A system according to claim 1 wherein said resection guide has ~~is~~ a guiding slot.

15. (AMENDED) A system according to claim 1 further comprising a plane probe, said plane probe including a planar surface and coupling means for coupling said plane probe ~~it~~ to a computer navigation tracker.

18. (AMENDED) A system according to claim 16 wherein said three degrees of freedom are infinitely adjustable ~~variable~~.

27. (AMENDED) A system according to claim 16 further

comprising a plane probe, said plane probe including a planar surface and coupling means for coupling said plane ~~it~~ to a computer navigation tracker.

30. (AMENDED) A system according to claim 2928 wherein said femoral anchoring means comprises ~~is~~ a pin.

31. (AMENDED) A system according to claim 2928 wherein said tibial anchoring means has an angled body and a side slot adapted to receive a pin.

42. (AMENDED) A system according to claim 28 further comprising a plane probe, said plane probe including a planar surface and coupling means for coupling said plane probe ~~it~~ to a computer navigation tracker.

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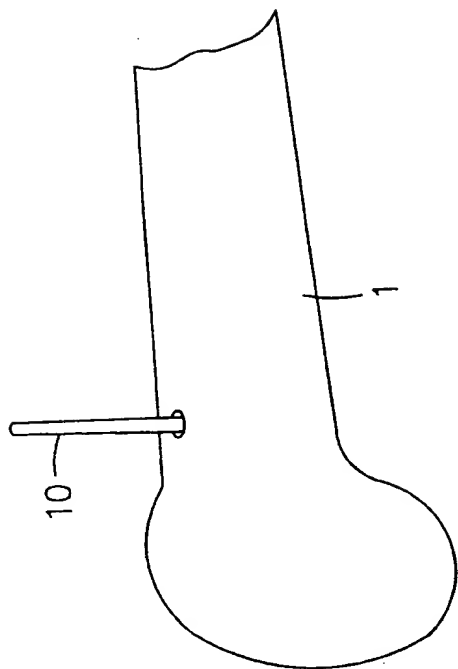


FIG. 2

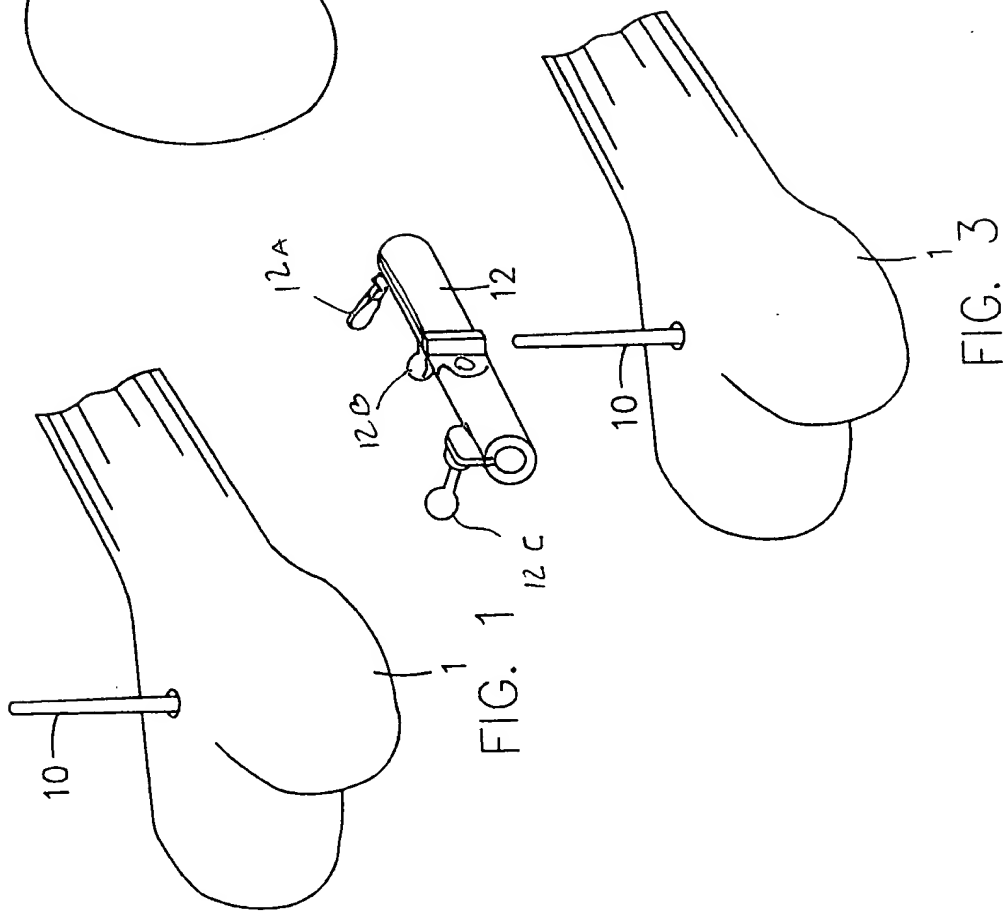


FIG. 1

FIG. 3

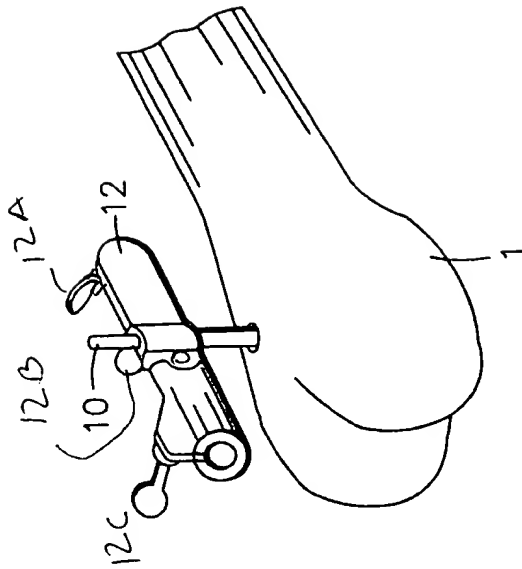


FIG. 4

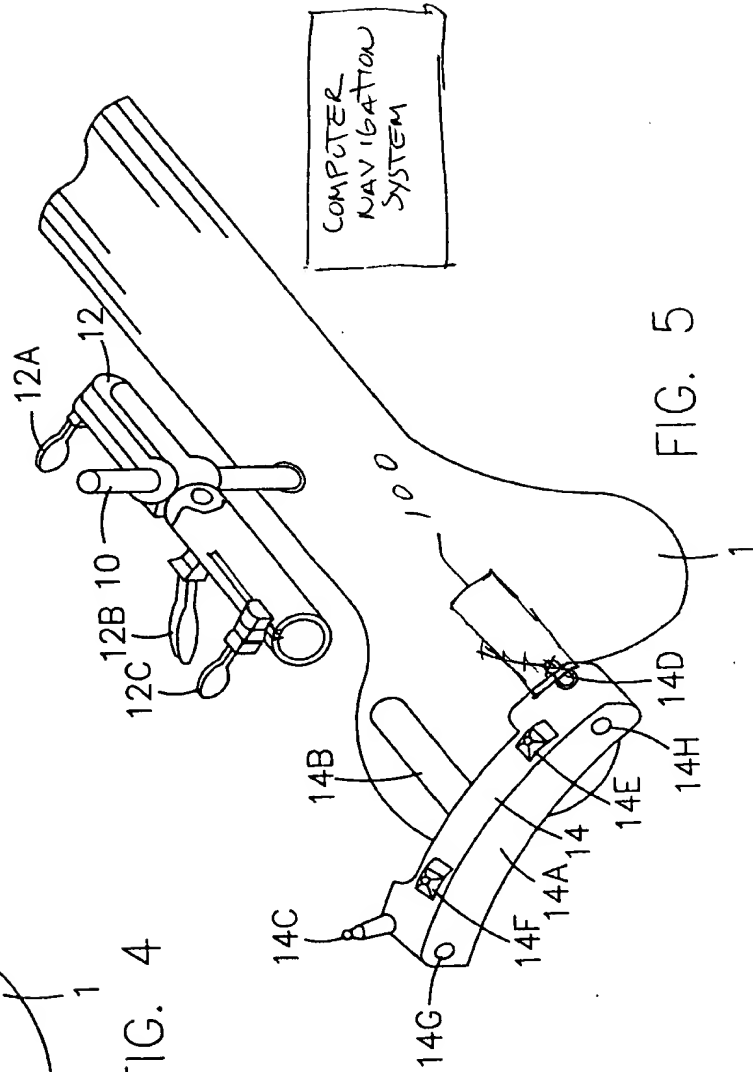


FIG. 5



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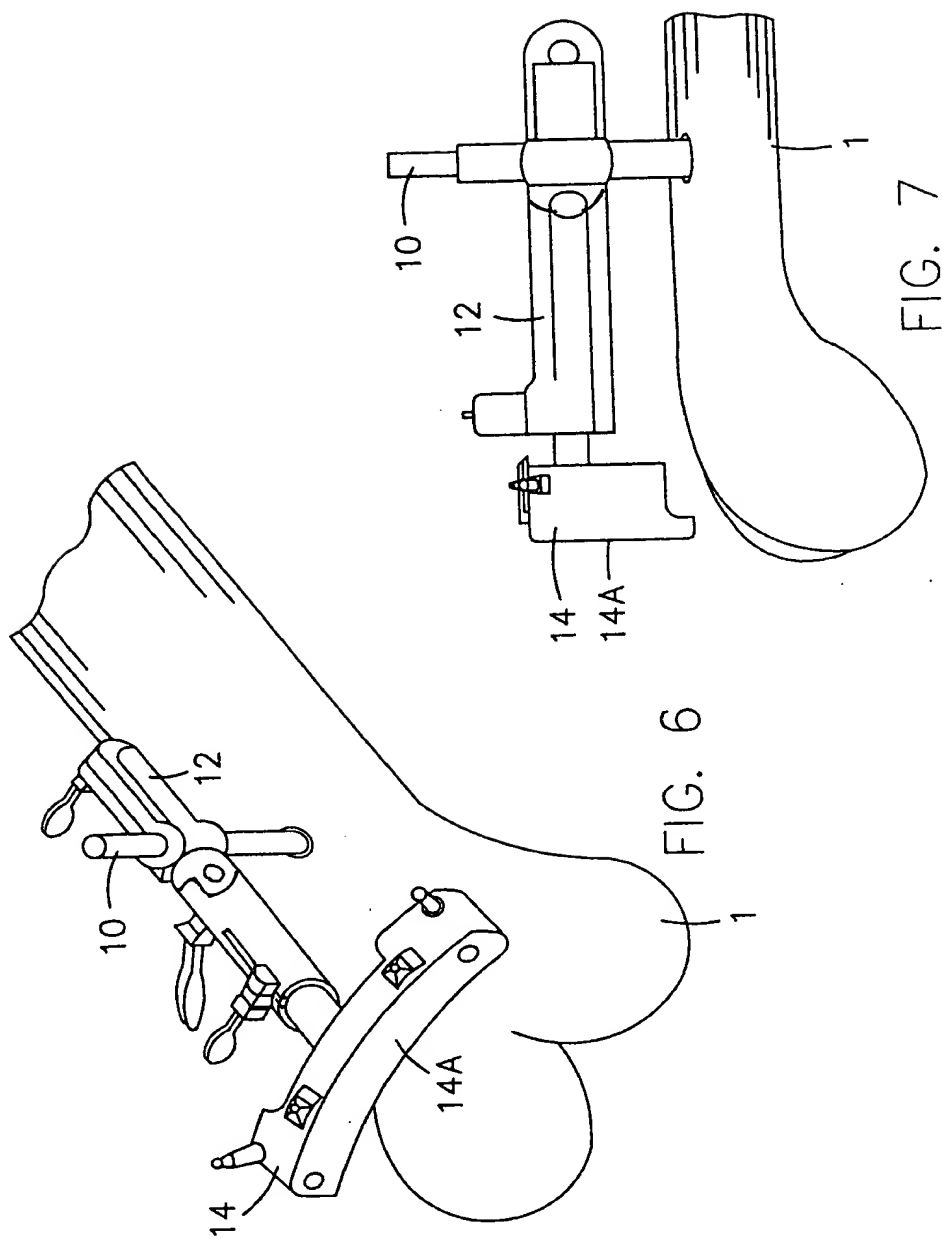


FIG. 6

FIG. 7



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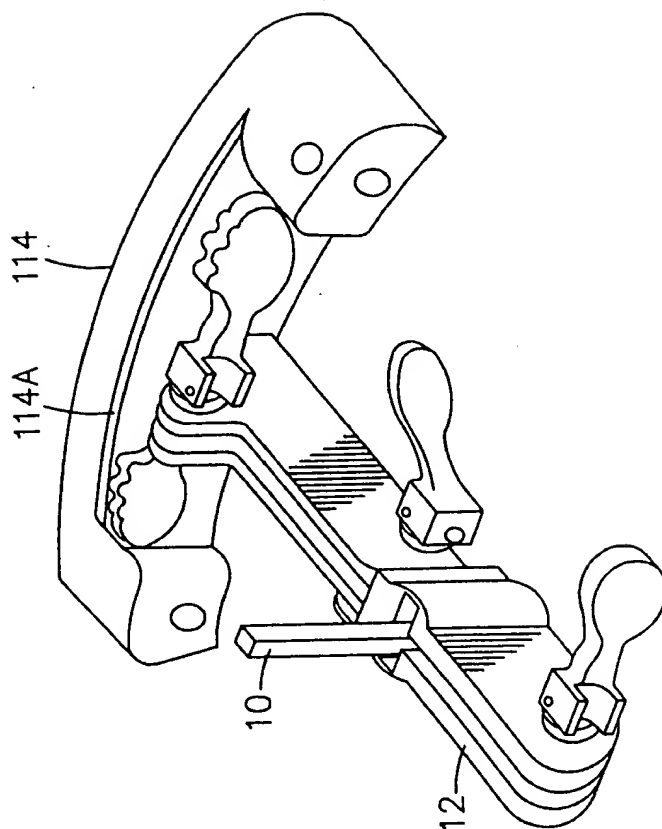


FIG. 8



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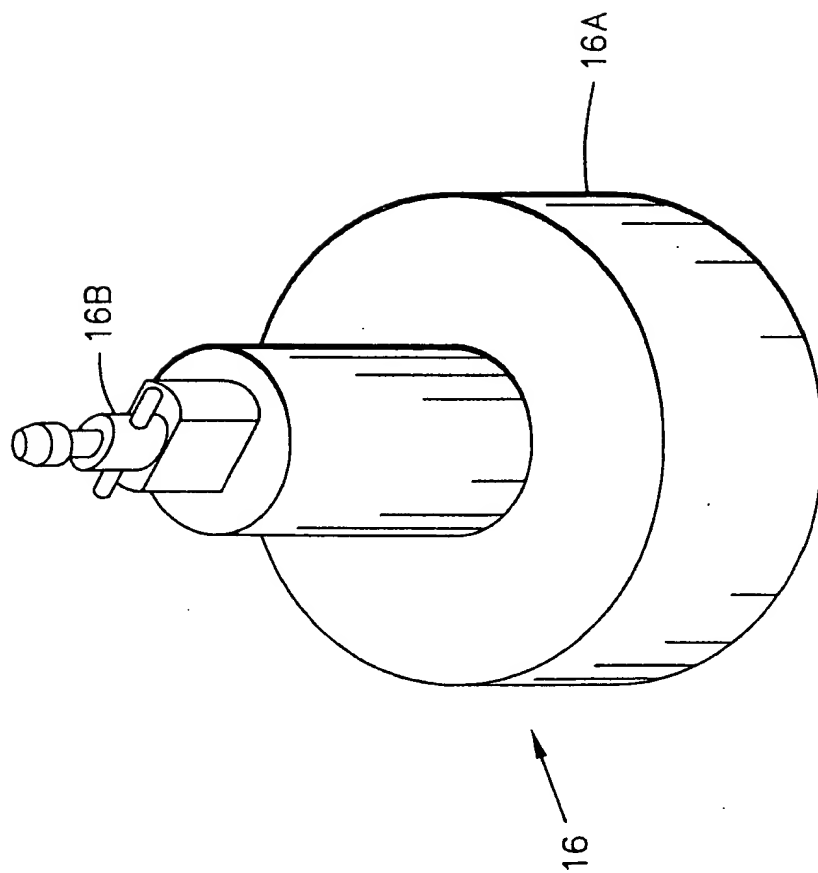


FIG. 9



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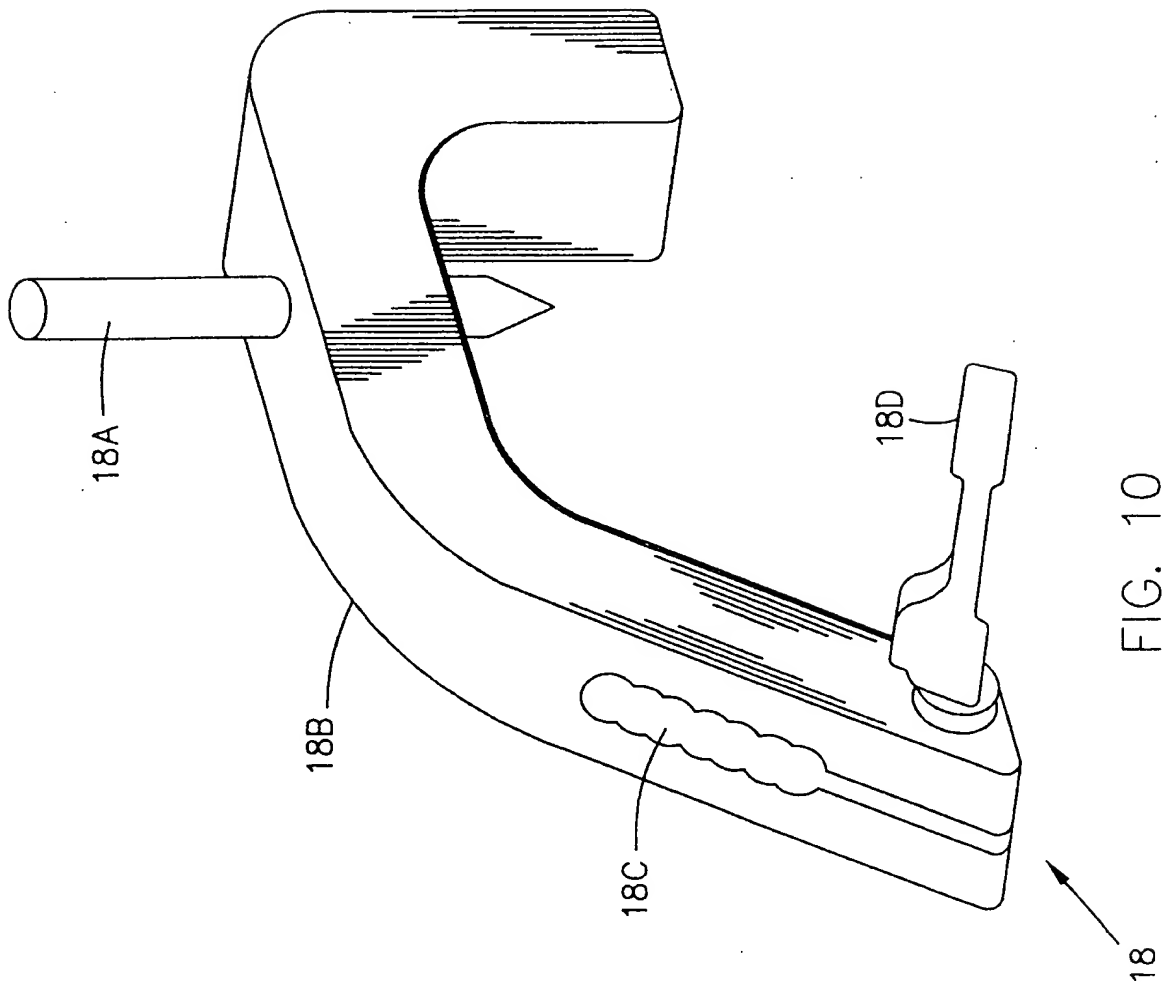


FIG. 10



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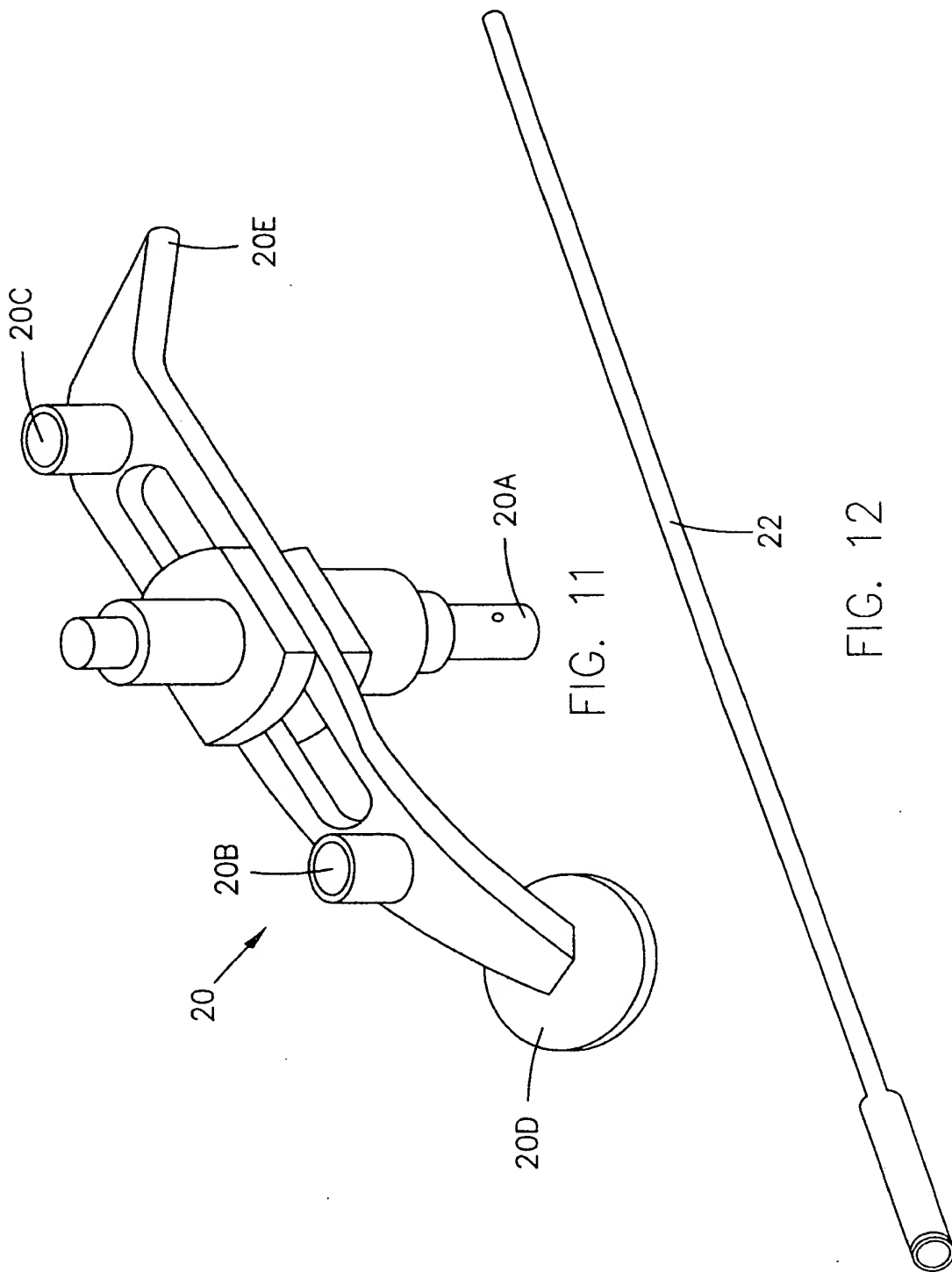


FIG. 11

FIG. 12

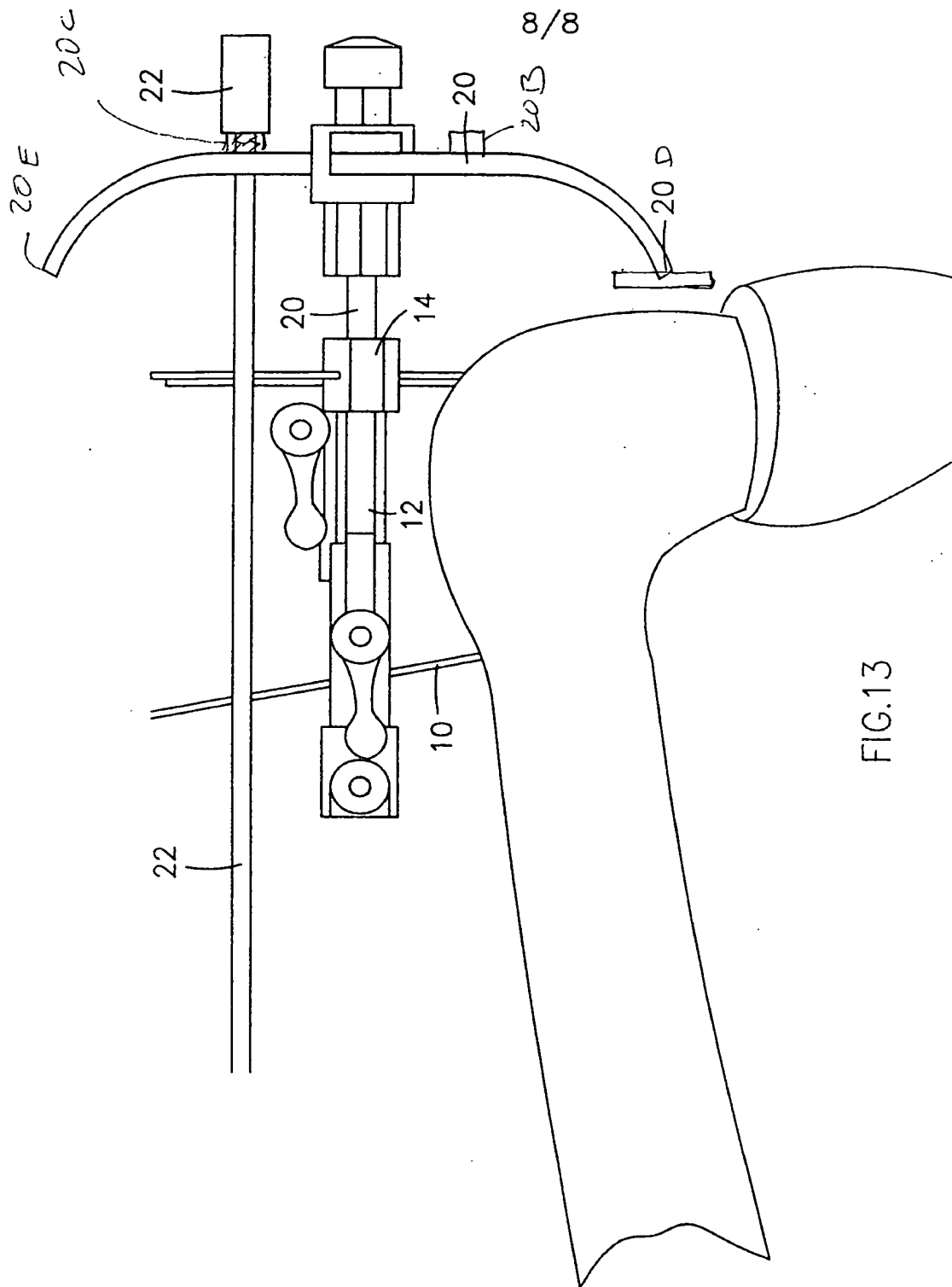


FIG.13

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